

### **REMARKS**

This responds to the Office Action mailed on March 30, 2007.

Claims 22, 23, 45 and 46 are canceled and claims 58-61 are added. As a result, claims 1-21, 24-44, 47-57, 58-60 and 61 are now pending in this application. However, the Examiner has withdrawn claims 47-57 from consideration as a result of the restriction requirement. Therefore, claims 1-21, 24-44, 58-60 and 61 are now under examination.

Support exists for claims 58-61 throughout the specification and claims as originally filed, for example, the specification at pages 9-13, original claim 55, the Examples and Figures (see, e.g., FIG. 2A, 2C, 2E, 3B, 3C, 4A, 5A, 6B and accompanying text).

Claims 1-4, 6, 13-18, 24-27, 29, 36-41 are amended. In particular, the phrase “or (a) subunit thereof” has been deleted from claims 1, 2, 13-18, 24, 25, 36-40 and 41. SEQ ID NO:3 and 4 have been deleted from claims 3 and 26. SEQ ID NO:9 has been deleted from claims 4 and 27. SEQ ID NO:6 has been deleted from claims 6 and 29.

Applicant submits that no new matter has been added to the claims or specification.

### ***Restriction***

Applicant acknowledges and understands that the Examiner has partially withdrawn the restriction requirement and will now search and examine claims 1-46 with respect to proepithelin (PEPI) alone or with secretory leukocyte protease inhibitor (SLPI), where PEPI is SEQ ID NO:1 and 2 and SLPI is SEQ ID NO:7.

### ***Title***

The Examiner has alleged that the title of the invention is not descriptive and has stated that a new title is required that is clearly indicative of the invention to which the claims are directed. This objection confuses Applicant because the title, “Use of Proepithelin to Promote Wound Repair and Reduce Inflammation,” is already clearly indicative of the claimed invention. Accordingly, no changes are needed and Applicant respectfully requests withdrawal of this objection to the title.

### ***Specification***

The disclosure was objected to because it contains an embedded hyperlink and/or other form of browser-executable code, on page 9, line 25. The Examiner cites MPEP § 608.01 as evidence allegedly requiring deletion of the hyperlink. This MPEP section recites the following:

When a patent application with embedded hyperlinks and/or other forms of browser-executable code issues as a patent (or is published as a patent application publication) and the patent document is placed on the USPTO web page, when the patent document is retrieved and viewed via a web browser, the URL is interpreted as a valid HTML code and it becomes a live web link. When a user clicks on the link with a mouse, the user will be transferred to another web page identified by the URL, if it exists, which could be a commercial web site. USPTO policy does not permit the USPTO to link to any commercial sites since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites.

Applicant submits that the specification as filed is fully enabled and that the information provided by the hyperlink is not essential for such enablement. While one of skill in the art is fully aware of the database provided by the National Center for Biotechnology Information (NCBI), the hyperlink citation is provided for the convenience of the reader. Moreover, the hyperlink is to <http://www.ncbi.nlm.nih.gov>, which is not a commercial website. Instead, it is a government (non-commercial) website providing information without any pressing any commercial issues or interests. Accordingly, Applicant submits that there is no requirement by law to remove this hyperlink.

Withdrawal of this objection to the specification is respectfully requested.

### ***Claim Objections***

Claims 3, 4, 6, 26, 27 and 29 were objected to because these claims recite non-elected sequences. These objections have been obviated by the pending claim set.

### ***§112 Rejection of the Claims***

Claims 1-46 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. According to the Examiner, the specification enables a method of wound healing in a mammal by administering the proepithelin polypeptide (PEPI) comprising the amino acid sequence set forth in SEQ ID NO:1 or 2 in combination with the secretory leukocyte protease

inhibitor (SLPI) comprising the amino acid sequence set forth in SEQ ID NO:7. However, the Examiner alleges that the specification does not enable all species and subunits of proepithelin (PEPI) or all species and subunits of secretory leukocyte protease inhibitor (SLPI).

Applicant submits that the specification fully enables all species and subunits of PEPI and SLPI. In particular, the specification describes different types of PEPI and SLPI and provides compositions and methods for using these PEPI and SLPI polypeptides for treating wounds and reducing inflammation. See specification generally and the Examples in particular.

The Examiner also alleges that the specification only enables use of PEPI and SLPI together. However this allegation is contrary to the evidence of record. In particular, Example 6 specifically shows that PEPI restores wound healing in SLPI-deficient mice (see also Fig. 7). Thus, even though SLPI is absent PEPI promotes wound healing. Therefore, the Examiner's statement that PEPI and SLPI must be used together is not accurate.

However, Applicant's specification also shows that SLPI has a role in wound healing. For example, specification also teaches that SLPI and PEPI interact and SLPI and PEPI together augmented exhibited enhanced neutrophil-inhibitory effects (see Example 5 and Fig. 5C). SLPI can also protect PEPI from elastase digestion (see, Example 3, Fig. 3B). Other PEPI and SLPI effects are described in the specification, for example, in the section entitled "Wound healing and inflammation." Thus, PEPI is effective without SLPI but SLPI has beneficial effects that can augment healing and reduce inflammation.

The specification therefore clearly enables the full scope of the invention. However, in order to expedite the allowance of this application, certain amendments have been made to the claims, for example, to comply with the restriction requirement.

Applicant submits that the claims are in condition for allowance and respectfully requests that this rejection under section 112, first paragraph, be withdrawn.

### **RESERVATION OF RIGHTS**

In the interest of clarity and brevity, Applicant may not have addressed every assertion made in the Office Action. Applicant's silence regarding any such assertion does not constitute any admission or acquiescence. Applicant reserves all rights not exercised in connection with this response, such as the right to challenge or rebut any tacit or explicit characterization of any

reference or of any of the present claims, the right to challenge or rebut any asserted factual or legal basis of any of the rejections, the right to swear behind any cited reference such as provided under 37 C.F.R. § 1.131 or otherwise, or the right to assert co-ownership of any cited reference. Applicant does not admit that any of the cited references or any other references of record are relevant to the present claims, or that they constitute prior art. To the extent that any rejection or assertion is based upon the Examiner's personal knowledge, rather than any objective evidence of record as manifested by a cited prior art reference, Applicant timely objects to such reliance on Official Notice, and reserves all rights to request that the Examiner provide a reference or affidavit in support of such assertion, as required by MPEP § 2144.03. Applicant reserves all rights to pursue any cancelled claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claim, as required by MPEP § 821.04.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (516) 795-6820 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

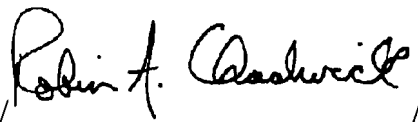
Respectfully submitted,

JING ZHU ET AL.

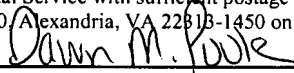
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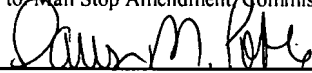
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Date June 28, 2007

By   
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**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22304-1450 on this 28<sup>th</sup> day of June 2007.





Name

Signature